



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

VIA ELECTRONIC MAIL

Mr. Barry White
Plant Manager
American Distillation, Inc.
1690 N.E. Royster Road
Leland, North Carolina 28451
barry@americandistillation.net

SUBJ: Request for Information
American Distillation, Inc., EPA ID Number NCR000001651

Dear Mr. White:

On May 8 and 9, 2018, the U.S. Environmental Protection Agency, along with the North Carolina Department of Environmental Quality, conducted a RCRA compliance evaluation inspection (CEI) at American Distillation, Inc. located in Leland, North Carolina to determine the facility's compliance status with the Resource Conservation and Recovery Act (RCRA) and The North Carolina Solid Waste Management Law (NCSWML), N.C.G.S. §§ 130A-17 to -28 and 130A-290 to -310 and applicable regulations.

The EPA received information from the New Jersey Department of Environmental Protection regarding non-manifested shipments of hazardous waste consisting of isopropyl alcohol/toluene/water mixtures. These shipments, which were made via a hazardous waste broker, Carolina Initiatives, from Veolia ES Technical Solutions (Veolia) in Middlesex New Jersey, were received by your facility.

These non-manifested shipments included materials which were previously shipped to Veolia as D001/F003/F005 hazardous waste from Pfizer Pharmaceuticals LLC in Barceloneta, Puerto Rico, under manifests numbered 000950423VES and 000950553VES. Documents obtained on May 9, 2018, at your facility indicate that the materials shipped as hazardous waste to Veolia were subsequently shipped, without a hazardous waste manifest, on bills of lading, via broker Carolina Initiatives to the Facility on September 28, 2017, October 2, 2017 and October 20, 2017. The materials were subsequently treated by your facility to remove water and toluene and returned to Carolina Initiatives.

The American Distillation, Inc. website describes operations which it can perform on organic-based materials that include distillation and dewatering. These operations were confirmed during EPA's May 8 and 9, 2018, CEI and through conversations with you.

Pursuant to Section 3007 of RCRA, 42 U.S.C. § 6927, American Distillation, Inc. is hereby directed to respond, fully and truthfully, within thirty (30) calendar days of receipt of this letter, to the Information

Request enclosed herein as Enclosure C (subject to the Instructions in Enclosure A and the Definitions in Enclosure B). Compliance with this request for information is mandatory, and information provided by American Distillation, Inc. may be used by the EPA in future enforcement actions. Failure to respond fully and truthfully to each and every question or information request within thirty (30) calendar days of receipt of this letter, or to adequately justify such failure to respond, may result in further enforcement action against American Distillation, Inc. by the EPA pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928.

Your response to this request for information should be mailed to:

Alan A. Annicella
Acting Chief
Chemical Safety and Land Enforcement Branch
Enforcement and Compliance Assurance Division
U.S. EPA, Region 4
61 Forsyth St., SW
Atlanta, Georgia 30303-3104

The information requested herein must be provided notwithstanding its possible characterization as confidential information or trade secrets. American Distillation, Inc. may, if desired, assert a business confidentiality claim covering part or all of the information requested, in the manner described in 40 C.F.R. § 2.203(b), by attaching to such information, at the time it is submitted, a suitable notice employing language such as trade secret or proprietary or company confidential. Information covered by such a claim will be disclosed by the EPA only to the extent and only by means of the procedures set forth in 40 C.F.R. Part 2, Subpart B. If no such claim accompanies the information when it is received by the EPA, it may be made available to the public by the EPA without further notice to American Distillation, Inc. The EPA will construe the failure to furnish a confidentiality claim with your response to this letter as a waiver of that claim. American Distillation, Inc. should read the above-cited regulations carefully before asserting a business confidentiality claim, since certain categories of information are not properly the subject of such a claim.

This Information Request is not subject to the approval requirement of the Paper Reduction Act of 1980, 44 U.S.C. § 3501 et seq. Should you have any questions on this matter, please contact Daryl R. Himes, of my staff, by phone at (404) 562-8614 or by email at himes.daryl@epa.gov.

Sincerely,

Alan A. Annicella
Acting Chief
Chemical Safety and Land Enforcement Branch

Enclosures
Attachments (2)

ENCLOSURE A

INFORMATION REQUEST

Instructions:

1. Identify the person(s) responding to these Information Requests on behalf of Respondent.
2. A separate response must be made to each of the Information Requests set forth herein.
3. Precede each answer with the number of the Information Request to which it corresponds.
4. In answering each Information Request question, identify all documents and persons consulted, examined, or referred to in the preparation of each response and provide true and accurate copies of all such documents.
5. If information not known or not available to you as of the date of submission of a response to this Information Request should later become known or available to you, you must supplement your response to the EPA. Moreover, should you find at any time after the submission of its response that any portion of the submitted information is false or misrepresents the truth; you must notify the EPA thereof as soon as possible.
6. For each document produced in response to this Information Request, indicate on the document, or in some other reasonable manner, the number of the question to which it responds.
7. Where specific information has not been memorialized in a document, but is nonetheless responsive to the Request, you must respond to the question with a written response.
8. If information responsive to this Information Request is not in your possession, custody or control, then identify the person from whom such information may be obtained.
9. If you have reason to believe that there may be persons able to provide a detailed or complete response to any Information Request question or who may be able to provide additional responsive documents, identify such persons and the additional information or documents that they may have.
10. The information requested herein must be provided even though the Respondent may contend that it includes possibly confidential information or trade secrets. You may, if you desire, assert a confidentiality claim covering part or all of the information requested, pursuant to Section 3007(b) of RCRA, 42 U.S.C. Section 6927(b), Sections 104(e)(7)(E) and (F) of CERCLA, 42 U.S.C. Sections 9604(e)(7)(E) and (F), and 40 C.F.R. Section 2.203(b), by attaching to such information at the time it is submitted, a cover sheet, stamped or typed legend, or other suitable form of notice employing language such as trade secret, or proprietary, or company confidential. Information covered by such a claim will be disclosed by the EPA only to the extent, and only by means, of the procedures set forth in statutes and regulation set forth above. If no such claim accompanies the information when it is received by the EPA, it may be made available to the public by the EPA without further notice to you. You should read the above cited regulations carefully before asserting a business confidentiality claim, since certain categories of information are not properly the subject of such a claim.

ENCLOSURE B

INFORMATION REQUEST

Definitions:

The following definitions shall apply to the following words as they appear in this Enclosure.

1. The terms AND and OR shall be construed either disjunctively or conjunctively as necessary to bring within the scope of this Information Request any information which might otherwise be construed to be outside their scope.
2. The term DISPOSAL shall mean the discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any water, including groundwater.
3. The term DOCUMENT and DOCUMENTS shall include writings of any kind, formal or informal, whether or not wholly or partially in handwriting (including by way of illustration and not by way of limitation), any invoice, receipt, endorsement, check, bank draft, canceled check, deposit slip, withdrawal slip, order, correspondence, record book, minutes, memorandum of telephone and other conversations including meetings, agreements and the like, diary calendar, desk pad, scrapbook, notebook, bulletin, circular, form, pamphlet, statement, journal, postcard, letter, telegram, telex, report, notice, message, analysis, comparison, graph, chart, inter-office or intra-office communications, photostat or other copy of any documents, microfilm or other film record, photograph, sound recording on any type of device, punch card, disc or disc pack, tape or other type of memory generally associated with computers and data processing (together with the programming instructions and other written material necessary to use punch card, disc, disc pack, tape or the type of memory) including; (a) every copy of each document which is not an exact duplicate of a document which is produced, (b) every copy which has any writing, figure, notation, annotation, or the like of it, (c) drafts, (d) attachments to or enclosures with any document, and (e) every document referred to in any other document.
4. The term FACILITY shall mean American Distillation, Inc. (ADI), located at 1690 N.E. Royster Road, Leland, North Carolina.
5. The term GENERATION shall mean any act or process which produces hazardous waste as identified or listed in 40 C.F.R. Part 261 or an act which first causes a hazardous waste to become subject to regulation.
6. The term HAZARDOUS SUBSTANCE means: (a) any substance designated pursuant to Section 311(b)(2)(A) of the Federal Water Pollution Control Act; (b) any element, compound, mixture, solution, or substance designated pursuant to Section 102 of CERCLA; (c) any hazardous waste having the characteristics identified under or listed pursuant to Section 3001 of RCRA (but not including any waste the regulation of which under RCRA has been suspended by Act of Congress); (d) any toxic pollutant listed under Section 307(a) of the Federal Water Pollution Control Act; (e) any hazardous air pollutant listed under Section 112 of the Clean Air Act; and (f) any imminently hazardous chemical substance or mixture with respect to which the Administrator of the EPA has taken action pursuant to Section 7 of the Toxic Substances Control Act. The term does not include petroleum, including crude oil or any fraction thereof which is not otherwise

ENCLOSURE B

specifically listed or designated as a hazardous substance under subparagraphs (a) through (f) of this paragraph, and the term does not include natural gas, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas). HAZARDOUS SUBSTANCE shall include any mixtures of such hazardous substances with any other substances including petroleum products.

7. The term HAZARDOUS WASTE means a hazardous waste as defined in 40 C.F.R. § 261.3.
8. The term IDENTIFY means, with respect to a natural person, to set forth the person's name, present or last known business address and business telephone number, present or last known home address and home telephone number, and present or last known job title, position or business.
9. The term IDENTIFY means, with respect to a corporation, partnership, business trust or other associate of a business entity (including a sole proprietorship), to set forth its full name, address, legal form (e.g., corporation, partnership, etc.), organization, if any, and a brief description of its business.
10. The term IDENTIFY means, with respect to a document, to provide its customary business description, date, number, if any (invoice or purchase order number), the identity of the author, addressor, addressee and/or recipient, and the substance or the subject matter.
11. The term PERSON includes, in the plural as well as the singular, any natural person, firm, unincorporated associate partnership, corporation, trust or other entity.
12. The term POLLUTANT or CONTAMINANT shall include, but not be limited to, any element, substance, compound or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including a malfunction in reproduction) or physical deformation in such organisms or their offspring; except that the term POLLUTANT or CONTAMINANT shall not include petroleum, including crude oil or any fraction thereof which is not otherwise specifically listed or designated as a hazardous substance under subparagraphs (a) through (f) of Definition 5 above, and shall not include natural gas, liquefied natural gas, or synthetic gas of pipeline quality (or mixtures of natural gas and such synthetic gas). POLLUTANT or CONTAMINANT shall include any mixtures of such pollutant and contaminants with other substances, including petroleum products.
13. The term RELEASE shall include any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment, including the abandonment or discharging of barrels, containers, and other closed receptacles containing any hazardous substance or pollutant or contaminant.
14. The term TRANSACTION or ARRANGEMENT shall mean every separate agreement, act, deal, instance or occurrence.
15. The term YOU or RESPONDENT shall mean the addressee of this Information Request, the addressee's officers, managers, employees, contractors, trustees, successors, assigns, and agents.

ENCLOSURE C

INFORMATION REQUEST

Requests:

- 1) Please submit all shipping documents from January 1, 2019, through the date of this letter for all solvents or solvent mixtures (including water) sent to the Facility for distillation and/or dewatering.
- 2) Please ensure that all documents submitted as part of Request Number 1 clearly identify the person (name, address, city, state, zip, phone number) responsible for producing or generating the solvent or solvent mixtures (including water). For those documents that do not clearly identify the person responsible for producing or generating the solvent or solvent mixtures (including water), please provide additional information which identifies the person from which the shipment was initiated.
- 3) Please submit all documents which correspond to each shipment provided in Request Number One that classifies or identifies all solvents or solvent mixtures (including water) accepted by the Facility from a person. At a minimum this should include:
 - a. The description from the person of the process in which the solvent or solvent mixtures (including water) was generated;
 - b. Designation of the solvent or solvent mixtures (including water) by the person as a waste, product, etc.;
 - c. Analysis of the solvent or solvent mixtures (including water) prior to acceptance; and
 - d. All other related documents.

Background for Request 4 – 10

On May 12, 2015, and January 10, 2017, ADI sent identical letters (copies attached) to Mr. Lior Busel, the Environmental Health and Safety Director of RTI Surgical, Inc. (RTI) in Alachua, Florida regarding ADI's wish to purchase isopropanol (IPA) product from RTI. In the letters, ADI states its desire to purchase the product isopropyl alcohol from RTI which "will be used in its entirety as is as a tank cleaner or wash (windows and filters)". On May 16, 2017, ADI sent a similar letter (copy attached) to RTI to purchase their acetone product. In the May 16, 2017, letter, ADI states that "the acetone will be used in its entirety as is as Tank Pickling (conditioning) after Tank Cleaning".

On March 7, 2019, ADI submitted records to EPA in response to a December 18, 2018 information request letter pursuant to Section 3007 of RCRA. The records provided by ADI on March 7, 2019 and additional records provided to EPA by RTI during a November 20, 2019, RCRA compliance evaluation inspection (CEI) indicate from January 6, 2015, through November 20, 2019, there were multiple individual shipments of IPA and acetone from RTI to ADI.

On November 20, 2019, during the RCRA CEI at RTI, a phone conversation was held on speaker phone between Daryl Himes of the EPA and Barry White, General Manager of ADI, regarding the shipments of IPA and acetone that were transported from RTI to ADI. Also present during the call were representatives of RTI and the Florida Department of Environmental

ENCLOSURE C

Protection. During the call, Mr. White was asked if the IPA and acetone mixtures received by ADI from RTI were being used as a product or were being distilled upon their receipt at ADI. Mr. White stated that the materials were being distilled upon their receipt from RTI and resold.

- 4) Did ADI have a contract with RTI as described in 40 CFR § 261.2(f) during the time it was receiving shipments of IPA or acetone from RTI? If yes, please provide a copy of that contract.
- 5) Please provide any and all documents which identify shipments of IPA or acetone received by ADI from RTI that were used by ADI, as is, before being distilled and sold to an off-site facility during the past 5 years.
- 6) Please identify how each shipment identified in request Number 5 were used by ADI pursuant to the contract specified by request Number 4.
- 7) Please submit any and all documents related to the sale of IPA or acetone (i.e. purchase orders, bills of lading) received by ADI from RTI to an off-site facility which were not distilled by ADI before being resold during the past 5 years.
- 8) Please provide any contractual agreements between ADI and any off-site brokers, which have sold materials containing IPA or acetone to ADI, that were generated by RTI.
- 9) Please provide copies of any and all letters sent to any and all of your customers during the past 5 years, similar to the two attached letters, which state ADI's desire to purchase ADI's potential customer's materials for use, as is, by ADI for any purpose.
- 10) Please provide records documenting ADI's tank cleaning operations which identify the following: the tank(s) at ADI being cleaned, the origin of solvents used for cleaning, the volume of solvent used for cleaning and the final disposition of the solvents used for cleaning.

AMERICAN DISTILLATION INC

1690 NE ROYSTER ROAD
PO BOX 400
LELAND, NC 28451
(910) 371-0993 FAX (910) 371-2971

May 12, 2015

Mr. Lior Busel
Environmental Health & Safety Director
RTI Surgical, Inc.
11621 Research Circle
Alachua, FL 32615

RE: Your product 50% Isopropanol/50% Water

Dear Mr. Busel:

American Distillation, Inc. (ADI) wishes to purchase your Isopropanol (IPA) product. This IPA product will be used in its entirety as is as a tank cleaner or a wash (windows and filters). There is a third application where the IPA could function as a raw material, such as in isopropyl acetate manufacture, but market economics and material availability would dictate the suitability or not of this material for that application. Dedicated storage exists for this material to ensure material integrity.

ADI appreciates the opportunity and looks forward to doing business in the near future. Please do not hesitate to contact me if there are any questions you may have.

Regards,

A handwritten signature in blue ink, appearing to read 'Barry White', is written over a faint, circular embossed seal.

Barry White
Plant Manager

AMERICAN DISTILLATION INC

1690 NE ROYSTER ROAD

PO BOX 400

LELAND, NC 28451

(910) 371-0993 FAX (910) 371-2971

MAY 16, 2017

Mr. Lior Busel

Environmental Health & Safety Director

RTI Surgical, Inc.

11621 Research Circle

Alachua, FL 32615

RE: Your product Acetone

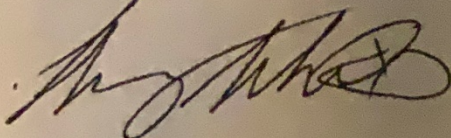
Dear Mr. Busel:

American Distillation, Inc. (ADI) wishes to purchase your Acetone product. This Acetone product will be used in its entirety as is as Tank Pickling (conditioning) after Tank Cleaning. Dedicated storage exists for this material to ensure material integrity.

ADI appreciates the opportunity and looks forward to doing business in the future. Please do not hesitate to contact me if there are any questions you may have,

Regards,

Barry White



Plant Manager